

Serial No.: 10/580,979

Confirmation No.: 9290

371(c) filing date: April 9, 2007

For: **REPLICATION COMPETENT HEPATITIS C VIRUS AND METHODS OF USE**

Remarks

This is responsive to the Office Action mailed March 9, 2009 and supplements the Amendment and Response filed June 9, 2009. Claims 1, 14, 18, 26, and 33 having been amended, claims 9-13, 37-40, and 44-46 having been canceled, without prejudice, the pending claims are claims 1-8, 14-36, and 41-43. Reconsideration and withdrawal of the rejections are respectfully requested.

This supplemental reply includes an amendment to claim 14 that was not present in the reply filed June 9, 2009.

Support for the amendment of claim 1 may be found in the specification at, for instance, page 11, line 32 through page 12, line 16, and page 17, line 21 through page 18, line 22.

Support for the amendment of claims 14, 18, 26, and 33 may be found in the specification at, for instance, page 17, line 21 through page 18, line 22.

Support for the additional amendment of claim 14 may be found at, for instance, originally filed claims 1, 18, and 26.

Elections/Restrictions

The Applicants appreciate the clarification that claims 34-36 are part of Group I and that claims 44-46 are part of Group II.

Sequence Requirements

A sequence listing was submitted April 8, 2009. It is the Applicant's understanding that this application now complies with the requirements of 37 C.F.R. §§1.821 through 1.825.

Specification

The specification has been amended at the paragraphs beginning at page 17, line 21 and page 19, line 1, to delete "at <http://www.ncbi.nlm.nih.gov/gorf/bl2.html>" and insert -- through the World Wide Web at the internet site maintained by the National Center for Biotechnology Information, National Institutes of Health --. The phrase "National Center for Biotechnology

Information" is supported by "ncbi" in the URL and the phrase "National Institutes of Health" is supported by "nih" in the URL.

The 35 U.S.C. §112, Second Paragraph, Rejection

The Examiner rejected claims 1-8, 14-35 and 41-43 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This rejection is respectfully traversed.

It is the Applicants' position that the claims set forth the subject matter that applicants regard as their invention, and the claims particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. In the interests of furthering prosecution, independent claims 1, 14, 18, 26, and 33 have been amended to recite "wherein the amino acid sequence of the hepatitis C virus polyprotein and the amino acid sequence of SEQ ID NO:2 have at least about 90% identity."

The Office Action states at paragraph 7 that the novelty of the claimed HCV mutant has not been evaluated. If the next Office Action includes an art-based rejection, it is respectfully requested that the next Office Action not be final, as the Applicant is entitled to a full and fair hearing and full development of any issue brought up during prosecution. M.P.E.P §706.07.

Reconsideration and withdrawal of the present rejection is respectfully requested.

The 35 U.S.C. §101 Rejection

The Examiner rejected the invention of claims 1-2, 4-8, and 41 under 35 U.S.C. §101 directed to non-statutory subject matter. This rejection is respectfully traversed.

In the interests of furthering prosecution, claim 1 has been amended to recite "wherein the replication competent polynucleotide is isolated." Thus, claim 1 is directed to statutory subject matter. Each of claims 2, 4-8, and 41 depends, directly or indirectly, from claim 1 and, therefore, are likewise directed to statutory subject matter.

Reconsideration and withdrawal of the present rejection is respectfully requested.

Supplemental Amendment and Response

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Summary

It is respectfully submitted that the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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Date

June 17, 2009

CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17th day of June, 2009.

By: David L. Provence

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